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| 09/476,485 | 12/30/1999 | M. Gabriella Colucci | 108.236.119 | 7906 |
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| NANCY CHIU PH D | | | EXAMINER | |
| HALE AND DORR LLP 60 STATE STREET | | | BELYAVSKYI, MICHAIL A | |
| BOSTON, MA 02109 | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | , 7 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| Application No. Option Summary Display Option Opt | | | | | | | |
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| Examiner | | | Application No. | Applicant(s) | | | |
| Claim(s) | | | 09/476,485 | COLUCCI ET AL. | | | |
| - The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Earthwist of the membry be available author the provisions of 3 CFR 1.136(a). In ore-ent, however, may a reply be timely fitted Earthwist of the membry be available author the provisions of 3 CFR 1.136(a). In ore-ent, however, may a reply be timely fitted If the period for reply specified above it is set from thirty (20) days, a reply within the statutory minimum of thirty (30) days with be considered fromly. If the period for reply specified above it is set from the statutory period will agree and all displaced from the control and the statutory minimum of thirty (30) days with be considered fromly. If the period for reply specified above it is set from the statutory period will agree and all displaced from the statutory minimum of thirty (30) days with be considered fromly. If the period for reply specified above it is an above it is an application. A proper period from the period of the communication of the communication of the resulting date of the communication of the d | | | Examiner | Art Unit | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MALLING DATE OF THIS COMMUNICATION. 1- Extrusions of time may be audited under the constituence of 3 CFR 1.136(a). In no event, however, may a reply be limety filed after SIX (b) MONTHS from the mailing date of this communication. 1 the period for reply specified above, the materium statutory period will apply a SIX (d) MONTHS from the mailing date of this communication. 1 the period for reply specified above, the materium statutory period will apply a SIX (d) MONTHS from the mailing date of this communication. 1 the period for reply specified above, the materium statutory period will apply a SIX (d) MONTHS from the mailing date of this communication, even if smally filed, may reduce any among platent term adjustment. See 37 CFR 1.704(b). Status 1 | | | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under be provisions of 3 CFR 1.13(g). In no event, however, may a raply be smely filed Extensions of time may be available under be provisions of 3 CFR 1.13(g). In no event, however, may a raply be smely filed If the period for raply specified above is less than the provision of the period for raply specified to be a best than the period for raply specified above is less than the period for raply with the statutory provision. If the period for raply specified above is the same statutory provided all apply and will exprise X(e) (MOXTHS to the healing date of this communication, even if through filed, may reduce any season about the communication even if the period for raply specified above. The maining date of this communication, even if through filed, may reduce any season about the communication even if the period of this communication even if the period of the period of the communication even if the period of the period of the period of the communication even if the period of the per | Period for | r Reply | ears on the cover sheet with the c | orrespondence address | | | |
| 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-61 is/are pending in the application. 4a) Of the above claim(s) 6-8 and 15-60 is/are withdrawn from consideration. 5) Claim(s) 1-5.9-14 and 61 is/are rejected. 7) Claim(s) is/are allowed. 6) Claim(s) 1-5.9-14 and 61 is/are rejected. 7) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 30 December 1999 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved by disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121. | A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
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| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. | | | | | | | |
| a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) All Interview Summary (PTO-413) Paper No(s) Notice of Draftsperson's Patent Drawing Review (PTO-948) | | | | | | | |
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| | 2) 🛛 Notice o | of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Pa | | | | |



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DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

Claims 1-61 are pending.

2. Applicant's election with traverse of Group I, claims 1-7, 9-14 and 61 in Paper No. 14 and Pv-FRIL (SEQ ID NO: 6) from *Phaseolus vulgaris* as species of FRIL family in Paper No.16 are acknowledged. Applicant traverse the Restriction Requirement on the grounds that the search of Groups I-II together would not constitute a serious search burden on the examiner and that search of the claims of Group I would provide useful information for the claims of Group II.

This is not found persuasive because the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed on the examiner by the examination Groups. The Inventions are distinct for reasons elaborated in the previous Office Action

The requirement is still deemed proper and is therefore made FINAL.

Upon further consideration, the prior art search was extended to include D1-FRIL (SEQ ID NO: 2) from *Dolichos lab lab* and Yam FRIL (SEQ ID NO:8) from *Sphenostylis stenocarpa* as species of FRIL family.

Claims 8 and 15-60 (non-elected Group II-VIII) and claims 6-7 (non-elected species of elected Group I) are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-5, 9-14 and 61 read on an essentially pure composition of one or more members of the FRIL family, wherein FRIL family member is Pv-FRIL (SEQ ID NO: 6) from *Phaseolus vulgaris* or D1-FRIL (SEQ ID NO: 2) from *Dolichos lab lab* and Yam FRIL (SEQ ID NO:8) from *Sphenostylis stenocarpa* are under consideration in the instant application.



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3. This application repeats a substantial portion of prior US Patent No.6,310,195 and adds and claims additional disclosure (members of the FRIL family of progenitor cell preservation factors from a legume) not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

4. Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.



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- 5. Applicant's IDS filed 3/21/01 (Paper No. 5), notes that an IDS was submitted with the prior application 08/881,189. However these citations have been crossed out as said references cited in said parent application cannot be found. Applicant is invited to resubmit such references to complete the instant file. The examiner apologizes for any inconvenience to applicant for having to resubmit such documents.
- 6. The use of the trademark FICOLL-PAQUE has been noted in this application o(page 68, line 3 and page 72, line 30 in particular). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112.

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 is indefinite and ambiguous in being dependent upon non-elected claim 57.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 9-14 and 61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an essentially pure composition of one or more members of the FRIL family of progenitor cell preservation factors, wherein FRIL is D1 –FRIL (SEQ ID No.2) from *Dolichos lab lab* or PV-FRIL (SEQ ID No.6) from *Phaseolus vulgaris* or Yam-FRIL (SEQ ID No. 8) from *Sphenostylis stenocarpa* that can be used to preserve progenitor cells



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does not reasonably provide enablement for an essentially pure composition of one or more members of any FRIL family of progenitor cell preservation factors, claimed in claim 1; or any mutant derived from any second member of the FRIL family, claimed in claim 7; or any fusion protein comprising a first and a second portion, wherein the first portion is derived from a second member of the FRIL family, claimed in claim 7 that can be used to preserve progenitor cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

The claims as written encompass the genus of FRIL family of polypeptide amino acid sequences. The genus encompasses peptides wherein such peptides have numerous differences in amino acid sequences at different position that were not disclosed (any mutant form of FRIL) including numerous differences in linear and conformational epitopes which are coupled with an unlimited number of polypeptides as fusion proteins.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the limited working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

Applicant discloses only FRIL from *Dolichos lab lab that* is D1 –FRIL (SEQ ID No.2), or PV-FRIL (SEQ ID No.6) from *Phaseolus vulgaris* or Yam-FRIL (SEQ ID No. 8) from *Sphenostylis stenocarpa* in the instant specification (see page 56, line 3-9; page 83, line 25-30, and page 121, lines 5-11. Applicant only taught that an essentially pure composition of D1 – FRIL (SEQ ID No.2) or PV-FRIL (SEQ ID No.6) or Yam-FRIL (SEQ ID No. 8) have a progenitor cell preservation activity (see Examples 1, 5 and 22 in particular). Applicant has not taught how to make and/or use an essentially pure composition of one or more members of *any* FRIL family of progenitor cell preservation factors, claimed in claim 1; or *any* mutant derived from any second member of the FRIL family, claimed in claim 7; or *any* fusion protein comprising a first and a second portion, wherein the first portion is derived from a second member of the FRIL family, claimed in claim 7 that have progenitor cell preservation activity. The structural and functional characteristics of said peptides are not defined in the claim. The disclosure of SEQ ID NOS: 2, 6 and 8 cannot support the entire genus of FRIL family of progenitor cell preservation factors derived from plant lectins. In addition, Moore (US Patent 6,084,060) teaches that whether plant lectins act on mammalian cells via de novo means, or



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simply mimic their functional mammalian homolog is not yet know. No lectin has been successfully developed as human therapeutics (see column 2, lines 24-30 in particular).

It is known in the art that even single amino acid changes or differences in a proteins amino acid sequence can have dramatic effects on the protein's function. For example, Mikayama et al. (PNAS, 1993. 90: 10056-10060) teach that the human glycosylation factor (GIF) protein differs from human macrophage migration inhibitory factor (MIF) by a single amino acid residue (see Figure 1 in particular). Yet, Mikayama et al. further teach that GIF is unable to carry out the function of MIF and MIF does not demonstrate GIF activity (see Abstract in particular).

Applicant is relying upon certain biological activities and the disclosure of a limited number of species to support an entire genus. It is well known that minor structural differences among even structurally related compounds or compositions can result in substantially different biology, expression, and pharmacology of proteins. Therefore, structurally unrelated *any* FRIL family of progenitor cell preservation factors ,claimed in claim 1; or *any* mutant derived from any second member of the FRIL family , claimed in claim 7; or *any* fusion protein comprising a first and a second portion, wherein the first portion is derived from a second member of the FRIL family , claimed in claim 7 encompassed by the claimed invention other than D1 –FRIL (SEQ ID No.2) from *Dolichos lab lab* or PV-FRIL (SEQ ID No.6) from *Phaseolus vulgaris* or Yam-FRIL (SEQ ID No. 8) from *Sphenostylis stenocarpa* would be expected to have greater differences in their activities.

Since the amino acid sequence of a polypeptide determines its structure and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functionality (e.g. binding of FRIL to a normally glycosylated FLT3 receptor, as stressed by Applicant is essential for the invention, see page 25, line 3-5 in particular) requires a knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification) and detailed knowledge of the ways in which a polypeptide's structure relates to it's functional usefulness. However, the problem of predicting polypeptide structure from mere sequence data of a single amino acid sequence and in turn utilizing predicted structural determinations to ascertain functional aspects the peptides and finally, what changes can be tolerated with respect thereto is complex and well outside the realm of routing experimentation.

Since the amino acid sequence of a polypeptide determined its structural and functional properties, predictability of which fragments will retain functionality requires knowledge of, and guidance with regard to, which amino acids in the polypeptide's sequence contribute to its structure, and therefore, function. The problem of predicting which fragments or derivatives of a protein will retain functionality and which will not is complex and well outside the realm of routine experimentation. Because of the lack of sufficient guidance and predictability in determining which structures would lead to functional proteins or peptides with the desired properties and that the relationship between the sequence of a peptide and it's tertiary structure



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(i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al, in <u>The Protein Folding Problem and Tertiary Structure Prediction</u>, 1994. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of proteins encompassed by the claimed invention.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed an essentially pure composition of one or more members of any FRIL family of progenitor cell preservation factors, or any mutant derived from any second member of the FRIL family, or any fusion protein comprising a first and a second portion, wherein the first portion is derived from a second member of the FRIL family in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. In re Fisher, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 1-5, 9-14 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: an essentially pure composition of one or more members of the FRIL family of progenitor cell preservation factors, wherein FRIL is D1 –FRIL (SEQ ID No.2) from *Dolichos lab lab* or PV-FRIL (SEQ ID No.6) from *Phaseolus vulgaris* or Yam-FRIL (SEQ ID No. 8) from *Sphenostylis stenocarpa* that can be used to preserve progenitor cells.

Applicant is not in possession of : an essentially pure composition of one or more members of any FRIL family of progenitor cell preservation factors or any mutant derived from any second member of the FRIL family or any fusion protein comprising a first and a second portion, wherein the first portion is derived from a second member of the FRIL family that can be used to preserve progenitor cells.



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The specification fails to define all members of the an essentially pure FRIL family of progenitor cell preservation factors or *any* mutant derived from any second member of the FRIL family or *any* fusion protein comprising a first and a second portion, wherein the first portion is derived from a second member of the FRIL family. The lack of sufficient limitations would therefore allow for all other FRIL family members. Therefore, the skilled artisan cannot envision all the contemplated FRIL possibilities recited in the instant claims.

Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See <u>Fiers v.</u> Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of a genus of protein sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.



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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-2, 4, 9-14 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Gowda et al. (Applicant IDS).

Gowda et al. teach an essentially pure composition of plant lectin from *Dolichos lab lab* (see entire document, Abstract in particular). It is noted that the amino-acid sequence of said lectin is essentially the same as SEQ ID NO:2 of the instant application. (see attaches sequence alignment). Since the office does not have a laboratory to test the reference plan lectin, it is applicant's burden to show that the reference lectin do not possess the same functional limitations as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 9- 14 are included because the claimed functional limitation would be inherent properties of the referenced composition because a pharmaceutical formulation comprising referenced essentially pure composition of plant lectin from *Dolichos lab lab* would inherently performed the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. an essentially pure composition of one or more members of the FRIL family) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see <u>Bristol-Myers Squibb Co. v. Ben Venue Laboratories</u>, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Further, a composition is a composition irrespective of its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference.

Claim 61 is included because a composition is the same composition irrespective of how it is made.

The reference teachings anticipate the claimed invention.

14. Claims 1-5, 9-14 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (Applicant IDS) as is evidenced by the known fact disclosed in specification on page 19, lines 17-25.



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Moore et al. teach an essentially pure composition of plant legume lectins that are the members of FRIL family derived from red kidney beans that have progenitor cell preservation activity. (see entire document).

The know fact disclosed in specification on page 19, lines 17-25 discloses that the FRIL family of progenitor cell preservation factors consists of a family of lectins isolated from beans, including a family of lectins isolated from *Dolichos lab lab*, or from *Phaseolus vulgaris* or from *Sphenostylis stenocarpa*.

It would be immediately evidenced to one of ordinary skill in the art at the time the invention was made that an essentially pure composition of plant legume lectins that derived from red kidney beans is a member of FRIL family of progenitor cell preservation factors including a family of lectins isolated from *Dolichos lab lab*, or from *Phaseolus vulgaris* or from *Sphenostylis stenocarpa*.

Claims 9- 14 are included because the claimed functional limitation would be inherent properties of the referenced composition because a pharmaceutical formulation comprising referenced essentially pure composition of plant lectin from red kidney beans would inherently performed the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. an essentially pure composition of one or more members of the FRIL family) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see Britol-Myers Squibb Co.v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Exparte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp.v. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co.v. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999). Further, a composition is a composition irrespective of its intended use. The term "pharmaceutical composition" carries little patentable weight in the absence of evidence of structural difference.

Claim 61 is included because a composition is the same composition irrespective of how it is made.

The reference teachings anticipate the claimed invention.

15. No claim is allowed.

16. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.



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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D. Patent Examiner Technology Center 1600 March 10, 2003

CHRISTINA CHAN

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600